



## WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

October 12, 2006

Sportron International, Inc.  
115 Industrial Blvd Ste. B  
McKinney, TX 75069

Dear Sir or Madam:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses <http://www.sportron.com> and [www.sportroninternational.com](http://www.sportroninternational.com) and has determined that the products Carbotone and Diabetes FoodMatrix™ Pack (also referred to on your web sites as the "Blood Sugar Pack") are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web sites establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

Examples of some of the claims observed on each of your web sites for your products include:

**Carbotone**

- "Experts all agree CarboTone is the nutritional support for millions who are alarmed about the growing threat of diabetes."
- "World renown [sic] nutritionist, Dr. Alan Tomlinson said recently at a Wellness Symposium, 'Carbotone™ is the most advanced nutritional product that has been scientifically developed to intervene and assist in cases of abnormal sugar metabolism.'"

[following the sentence "One of the major active ingredients in Carbotone is Glucosol™"]

- "A clinical study...concluded, 'the average blood glucose level dropped 31.9% with a 32 mg glucosol dose per day after 30 days.'"
- "Reported Benefits from Glucosol Clinical Study:
  - Lowering blood glucose levels in type 2 diabetics.
  - Regaining blood glucose balance in type 2 diabetics."

[following the sentence "Another major ingredient in Carbotone is Food Matrix Chromium"]

- “Chromium, ... using Sportron's Food Matrix technology, is the most effective form of Chromium because it contains Chromium as Glucose Tolerance Factor (GTF).

...

Studies indicate that GTF stimulates insulin activity directly by binding to both insulin itself and specific insulin receptors. When Chromium is supplemented in the form of GTF and it is active in the human body, it will produce the following results: Controls blood glucose...Reduces arteriosclerosis...Increases resistance to infection”

Both of your web sites, under the heading "Products: Carbotone," also contain links to studies on diabetes. These links constitute implied claims that your product is intended for use in the cure, mitigation, treatment, or prevention of diabetes, a disease. An example of these links includes:

- a link to a study titled "Antidiabetic activity of a standardized extract (Glucosol) from Lagerstroemia speciosa leaves in Type II diabetics" [Glucosol is identified on your site as a major ingredient in Carbotone];

#### **Diabetes FoodMatrix™ Pack (also referred to as the "Blood Sugar Pack")**

- "Sportrons's Blood Sugar Pack has been specifically designed to help support type 2 diabetics."
- "Who should take the Blood Sugar Pack? Anyone suffering from unhealthy blood sugar levels ...."
- In addition, the name of your product, Diabetes FoodMatrix™ Pack, suggests that it is intended for use in the cure, mitigation, treatment, or prevention of diabetes, a disease.

Both of your web sites, under the heading "Products: Blood Sugar Pack," also contain links to brochures on diabetes. These links constitute implied claims that your product is intended for use in the cure, mitigation, treatment, or prevention of diabetes, a disease. Examples of these links include:

- a link to your brochure titled "Diabetes, 'A National Epidemic'";
- a link to your brochure titled "FoodMatrix Provides Hope for Diabetics."

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the products are also “new drugs” under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Your products “Carbotone” and “Diabetes FoodMatrix™ Pack” are also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. While reviewing your web sites, we noticed that you promote other products for disease treatment and/or prevention. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your web sites, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

Failure to promptly correct the violations specified above may result in enforcement action without further notice. Enforcement action may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.

Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to correct these violations, including the steps taken to assure that similar violations do not recur. Include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be addressed to Kristen Moe, Compliance Officer, Food and Drug Administration, Division of Compliance and Enforcement, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you prefer to electronically, send your e-mail to [kristen.moe1@FDA.HHS.GOV](mailto:kristen.moe1@FDA.HHS.GOV). If you have any questions concerning this letter, please contact Ms. Moe at 301-436-2064.

Sincerely,

Joseph R. Baca  
Director  
Office of Compliance  
Center for Food Safety  
and Applied Nutrition